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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,878	12/09/2003	Ruchika Singhal	1023-334US01	4796

28863 7590 05/27/2005
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EXAMINER

GREENE, DANA D

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,878

Applicant(s)

SINGHAL ET AL.

Examiner

Dana D. Greene

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-29-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13, and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Reischl et al. (US 6,176,879, hereinafter "Reischl"). Reischl is considered to disclose:

an implantable medical device (see abstract, Reischl). The disclosed medical implant is considered to anticipate the claimed implantable medical device because both have functional components separated into individual interconnected modules and a both have a smaller profile which allows the IMD to better fit into available body locations;

an implantable medical device comprising: at least two interconnected modules, each of the modules comprising a housing (see col. 3, ln. 45-63, Reischl). The disclosed electronic module and housing portion are considered to anticipate the claimed interconnected modules and housing because both configurations accept external leads and have a low profile and allow for deployment proximate to a treatment or monitoring site;

an overmold that at least partially encapsulates each of the housing, the overmold comprising a lead connection module for accepting an external lead (see col.

1, ln. 35-55 and col. 2, ln. 49-57, Reischl). The disclosed silastic jacket and the rigid material surrounding the housing is considered to anticipate the claimed overmold because all configurations hold the modules and housing in a fixed position relative to one another and can be made of a variety of materials that are flexible or rigid.

With reference to claim 2, Reischl is considered to disclose:

at least one module comprising a control module containing electronic components (see col. 2, ln. 49-57 and col. 3, ln. 52-60, Reischl). The disclosed electronic module is considered to anticipate the claimed module because both devices can monitor the electrical activity, regulate administration of therapy, or both.

Referring to claims 3, 9, and 13, Reischl is considered to disclose:

an overmold comprising a first material and a second material, and the lead connection module deployed within the first material (see col. 3, ln. 50-60, Reischl). The disclosed energy storage device is considered to anticipate the claimed lead connection module because both electrically and mechanically couple the lead to the implantable device components.

With reference to claims 4 and 10, Reischl is considered to disclose:

a first material comprising a non-elastomeric material (see col. 4, ln. 50-55, Reischl). The disclosed metallic materials are considered to anticipate the claimed non-elastomeric material because all are hard and can be shaped to conform to the shape of one of the modules such that the modules will be steady and secured.

Referring to claims 5-7, Reischl is considered to disclose:

a feed-through wire to electrically couple an external lead to an electronic component within the implantable medical device (see col. 4, ln. 11-24, Reischl). The disclosed connecting cable is considered to anticipate the claimed feed-through wire because both ensure an electrical connection.

With reference to claim 8, Reischl is considered to disclose:
an implantable medical device that has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters (see col. 2, ln. 26-28, Reischl).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reischl in view of Julian (US 5,489,225, hereinafter "Julian"). Reischl is considered to disclose the claimed invention as discussed above, under the anticipatory

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rejection, except for the claimed elastomeric and silicone material. However, Julian is considered to disclose the claimed material (see col. 1, ln. 35-40, Julian). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reischl with the silicone or elastomeric materials found in Julian for the purpose of encapsulating the housings with the specific overmold.

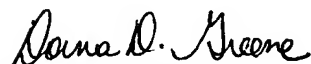
Claims 1-10, 13, and 14 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Reischl in view of Julian. Reischl is considered to disclose the claimed invention as discussed above under the anticipatory rejection. In this connection, Julian teaches a lead connection and modules configured to receive external leads (see col. 3, ln. 33-37, Julian). It would have been obvious to one of ordinary skill in the art to combine the implantable medical device teachings of Reischle with the lead connection configuration found in Julian for the purpose of electrically and mechanically coupling the lead to the components of the implantable medical device.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Dana D. Greene


George Manuel
Primary Examiner